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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE and ASTRAZENECA LP, KBI INC. and KBI-E, INC.,	07-CV-6790 (CM)(GWG)
Plaintiffs and Counterclaim Defendants,	
v.	
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.	**ELECTRONICALLY FILED**
Defendants and Counterclaim Plaintiffs.	

DRL DEFENDANTS' STATEMENT PURSUANT TO LOCAL CIVIL RULE 56.1 IN SUPPORT OF DRL'S MOTION FOR SUMMARY JUDGMENT

Pursuant to Local Civil Rule 56.1, Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "DRL") identify the following material facts about which DRL contends there does not exist a genuine issue to be tried.

I. This Action

1. Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively "AstraZeneca") filed this action on July 27, 2007 against defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "DRL"). Exhibit 11, AstraZeneca's July 27, 2007 Complaint.[1]

2. In AstraZeneca's Complaint AstraZeneca alleged on "information and belief" that the omeprazole magnesium capsules proposed in DRL's abbreviated new drug application, ANDA No. 78-878 ("DRL's ANDA"), infringe the two AstraZeneca patents-in-suit, United States Patent 5,900,424 ("the '424 patent", Exhibit 2) and United States Patent 5,690,960 ("the '960 patent", Exhibit 3). Exhibit 11, Complaint ¶¶ 27 and 47.

II. AstraZeneca Brought This Action To Obtain Discovery

3. AstraZeneca admitted in its Complaint that it brought this suit, in part, "to employ the judicial process and the aid of discovery" to obtain information about DRL's alleged infringement of the '424 patent and the '960 patent. Exhibit 11, Complaint ¶¶ 33 and 53.

III. DRL Has Asserted From The Start That AstraZeneca Has No Evidence

The September 21, 2007 Conference

4. Before the September 21, 2007 Conference conducted by the Court in this action, DRL suggested in a letter to the Court that this action could be resolved most expeditiously by an early motion for summary judgment. 2nd Weinstein Decl. ¶ 3 and Exhibit 1 thereto.

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[1] References to "Exhibit __" refer to the corresponding Exhibit attached to the Second Declaration of Louis H. Weinstein (Filed in Support of DRL's Motion for Summary Judgment) ("2nd Weinstein Decl.") submitted herewith.

5. At the September 21st Conference the Court directed the parties to assume that DRL had made its motion for summary judgment. 2nd Weinstein Decl. ¶ 4.

6. At the September 21st Conference DRL was ordered to produce samples of its omeprazole magnesium active ingredient and finished omeprazole magnesium ANDA capsules, DRL was ordered to respond to 10 Interrogatories that AstraZeneca was given leave to serve, and AstraZeneca was ordered to test DRL's samples by November 1, 2007. 2nd Weinstein Decl. ¶ 5.

7. At the September 21st Conference AstraZeneca asserted that its test procedures were work product. 2nd Weinstein Decl. ¶ 5

8. DRL produced a sample of its omeprazole magnesium active ingredient and a sample of its finished omeprazole magnesium ANDA capsules on September 24, 2007 and DRL responded to 10 AstraZeneca Interrogatories on November 1, 2007. 2nd Weinstein Decl. ¶ 6.

The November 7, 2007 Conference

9. AstraZeneca reported at the November 7, 2007 Conference that AstraZeneca had tested the samples provided by DRL, that DRL had responded to AstraZeneca's interrogatories, that AstraZeneca's test results did not show infringement and that further discovery was needed. 2nd Weinstein Decl. ¶ 7-8.

10. At the November 7, 2007 Conference AstraZeneca did not produce its test results and AstraZeneca asserted for a second time that its test procedures were work product. 2nd Weinstein Decl. ¶ 8.

11. At the November 7, 2007 Conference the Court ordered AstraZeneca to submit a list of additional discovery and to justify for each-and-every-claim why the discovery was needed to show infringement. 2nd Weinstein Decl. ¶ 9.

AstraZeneca's Explanation Of Infringement Discovery

12. AstraZeneca submitted its 43 page "Explanation of Infringement Discovery" (Exhibit 12) on November 19, 2007. 2nd Weinstein Decl. ¶ 11.

13. DRL submitted its "Reply to AstraZeneca's Explanation of Infringement Discovery" (Exhibit 13) on November 28, 2007. 2nd Weinstein Decl. ¶ 12.

The Court's Ruling On AstraZeneca's Request for Infringement Discovery

14. The parties received the Court's rulings on AstraZeneca's discovery requests on May 5, 2008 (Rulings On Astra-Zeneca's Request For Infringement Discovery) (the "Rulings") (Exhibit 14). 2nd Weinstein Decl. ¶ 13.

15. In the Court's Rulings the Court found that AstraZeneca did not comply with the Court's request that AstraZeneca justify any additional discovery on a claim-by-claim basis. Exhibit 14, Rulings ¶ 1. To the contrary, the Court explicitly found that AstraZeneca "had done nothing of the kind." Exhibit 14, Rulings ¶ 1.

16. The Court also found that "Astra-Zeneca's discovery requests smack of a fishing expedition." Exhibit 14, Rulings ¶ 2.

17. The Court found that AstraZeneca did not supply the Court "with anything other than an attorney's explanation about why the massive amount of discovery it seeks is necessary. . . ." Exhibit 14, Rulings ¶ 1.

18. The Court ordered some of the discovery requested by AstraZeneca. First, the Court ordered DRL to produce the documents from DRL's ANDA application and Drug Master File as requested in AstraZeneca's Discovery Requests Nos. 1 and 2. Exhibit 14, Rulings ¶ 3. The Court also allowed AstraZeneca to take an 8 hour deposition of one individual with

knowledge of the process by which DRL manufactures its ANDA product and the omeprazole magnesium that is used therein. Exhibit 14, Rulings ¶ 9.

19. DRL produced the additional documents required by the Court's Rulings before the allowed deposition. 2nd Weinstein Decl. ¶ 14.

20. On May 23, 2008, AstraZeneca took the deposition of Mr. Srinivas, a DRL employee who flew in from India. 2nd Weinstein Decl. ¶ 15.

21. Mr. Srinivas was knowledgeable regarding the process by which DRL manufactures its formulated omeprazole magnesium finished product and the process by which DRL manufactures the omeprazole magnesium active ingredient used in that product. Transcript of May 23, 2008 Deposition of Irukulla Srinivas, Exhibit 15, at p. 10, lines 13-20.

AstraZeneca Has Not Withdrawn Its Action

22. Despite DRL's samples, detailed interrogatory answers, relevant documents from DRL's ANDA Application, relevant documents from DRL's Drug Master File, and the deposition of a witness with knowledge of DRL's process, on June 16, 2008 AstraZeneca requested 9 categories of additional information and complained that "AstraZeneca has not received sufficient information to determine whether DRL infringes the patents-in-suit. . . ." Exhibit 16, 6/16/08 Letter from John Griem, p. 5.

23. On June 23, 2007 AstraZeneca informed DRL and the Court that AstraZeneca was not prepared to withdraw its action. Exhibit 17, 6/23/08 Letter from John Griem to Judge McMahon ("6/23/08 Letter").

24. In the 6/23/08 Letter AstraZeneca informed the Court that DRL would not voluntarily produce certain additional documents and information. *Id.*

25. On June 25, 2008 the Court endorsed the 6/23/08 Letter stating: "Then we will proceed to decide the motion to dismiss." Exhibit 18, 6/25/08 Memo Endorsement.

IV. AstraZeneca Cannot Meet Its Burden Of Proving Infringement

AstraZeneca Cannot Show That DRL's Omeprazole Magnesium Is More Than 70% Crystalline

26. The '424 patent issued from United States Patent Application 08/313,342 ("the '342 application" or alternatively, "the application for the '424 patent"). Exhibit 2, '424 Patent.

27. On December 9, 1996, the applicants submitted an "Amendment and Response" in the prosecution of the application for the '424 patent. Exhibit 4 ("12/9/96 Amendment and Response").

28. In the 12/9/96 Amendment and Response the applicants made the following statement when arguing in favor of the patentability of the application for the '424 patent:

> In the first instance, the present compound is a magnesium salt of omeprazole having more than 70% crystallinity as determined by x-ray powder diffraction. There is no disclosure in the primary reference pertaining to magnesium omeprazole salt of degree of crystallinity of more than 70%."

Exhibit 4, 12/9/96 Amendment and Response, p. 3.

29. On October 1, 1998 the applicants submitted a "Supplemental Amendment" in the prosecution of the application for the '424 patent. Exhibit 8 ("10/1/98 Supplemental Amendment").

30. In the 10/1/98 Supplemental Amendment the applicants made the following statement when arguing in favor of the patentability of the application for the '424 patent:

> The invention of the '342 application is directed to a magnesium omeprazole salt having a degree of crystallinity which is greater than 70% as measured by X-ray powder diffraction and to a process for making this novel form of magnesium omeprazole salt. Applicants submit that the crystallinity, or more precisely, the

> degree of crystallinity of a magnesium omeprazole salt is a critical feature determining whether such magnesium omeprazole substance is suitable for the full scale production of pharmaceutical preparations.

Exhibit 8, 10/1/98 Supplemental Amendment, pp. 3-4.

31. The '960 patent issued from United States Patent Application 08/313,036 ("the '036 application" or alternatively, "the application for the '960 patent"). Exhibit 3, '960 patent.

32. On October 7, 1996 the applicants submitted an "Amendment and Response" in the prosecution of the application for the '960 patent. Exhibit 5 ("10/7/96 Amendment and Response").

33. In the 10/7/96 Amendment and Response the applicants made the following statement when arguing in favor of the patentability of the application for the '960 patent:

> In the first instance, the instant oral formulation as presently claimed provides a core containing a magnesium omeprazole salt form with at least 70% crystallinity which advantageously affords greater stability and manufacture of coated tablets with enhanced acid resistance neither of which property is available with or even suggested by the prior art disclosure of omeprazole magnesium salts.

Exhibit 5, 10/7/96 Amendment and Response, p. 5.

34. Claim 1 of the '424 patent is limited to "[a]n omeprazole magnesium salt having a crystallinity which is higher than 70% as determined by x-ray powder diffraction." Exhibit 2, '424 patent, claim 1.

35. Claim 1 of the '960 patent includes the limitation that the core of the oral formulation contains "a magnesium salt of omeprazole said salt having more than 70% crystallinity as determined by x-ray powder diffraction." Exhibit 3, '960 patent, claim 1.

36. Claim 10 of the '960 patent includes the limitation of "forming a core material containing magnesium omeprazole salt said salt having at least 70% crystallinity as determined by x-ray powder diffraction." Exhibit 3, '960 patent, claim 10.

37. Claim 22 of the '960 patent includes the limitation that the core "comprises magnesium omeprazole salt having more than 70% crystallinity as determined by x-ray powder diffraction." Exhibit 3, '960 patent.

38. In the context of the claims of the '424 patent and the '960 patent, omeprazole magnesium which is less than 70% crystalline is not the equivalent of omeprazole magnesium which is more than 70% crystalline. Exhibit 4, p. 3; Exhibit 5, p. 5; Exhibit 8, pp. 3-4; 2nd Brittain Decl. ¶ 49.[2]

39. DRL made the following batches of omeprazole magnesium in connection with its DMF and ANDA filings: MG002A04 (also denoted OMG00604); MG003A04 (also denoted OMG00704); MG004B04 (also denoted OMG00804); MG018G05 (also denoted OMG01305); MG019G05 (also denoted OMG01405); MG020G05 (also denoted OMG01505); MG021G05 (also denoted OMG01605); MG030L05 (also denoted OMG02405); MG001A06 (also denoted OMG00106); MG002B06 (also denoted OMG00206); and EC6319 and each of the foregoing batches was tested for crystallinity by x-ray powder diffraction. Exhibit 6, DRL Defendants' Answers To The AstraZeneca Plaintiffs' First Set Of Interrogatories (Nos. 1-10), at p. 9, Answer to Interrogatory 9.

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[2] References to "2nd Brittain Decl. ¶__" refer to the corresponding paragraph in the Second Declaration of Harry Brittain, Ph.D. FRSC (Filed in Support of DRL's Motion for Summary Judgment) submitted herewith.

40. The results of the foregoing tests showed the omeprazole magnesium to be amorphous material with no crystallinity above a 1% limit of detection. *Id.*

41. The manufacture, importation into the United States, sale, offer for sale and use of the omeprazole magnesium capsules which are the subject of DRL's abbreviated new drug application No. 78-878 do not infringe claim 1 of the '424 patent or claims 1, 10 and 22 of the '960 patent, either literally or under the doctrine of equivalents. *See* preceding ¶¶ 26-40.

AstraZeneca Cannot Show That DRL Crystallizes Omeprazole Magnesium By The Addition Of Water

42. In the 10/1/98 Supplemental Amendment, the applicants made the following statement when arguing in favor of the patentability of the application for the '424 patent:

> A further distinguishing feature of the claimed process is the use of an aqueous alcohol solvent, e.g., methanol, to put omeprazole in solution and the subsequent use of a different solvent, i.e., water, to recover the crystalline magnesium omeprazole salt from solution. In contrast, the process of Example 6 of the '974 patent uses methanol as the sole solvent throughout the process. The use of different solvents as part of the controlled crystallization step of the '342 application is an important contribution to the recovery of crystals of the claimed magnesium omeprazole salt that are suitable as pharmaceutical substances.

Exhibit 8, 10/1/98 Supplemental Amendment, p. 5.

43. Claim 11 of the '424 patent contains the limitation of "crystallizing magnesium omeprazole by the addition of water." Exhibit 2, '424 patent, claim 11.

44. Claim 20 of the '424 patent requires crystallizing omeprazole magnesium by the addition of water. Exhibit 2, '424 patent, claim 20; Exhibit 8, p. 5; 2nd Brittain Decl. ¶ 35.

45. DRL prepares its solid omeprazole magnesium by evaporating the organic solvent in a specialized device called an Agitated Thin film Drier. Exhibit 6, Answer to Interrogatory 10, pp. 14-15; 2nd Brittain Decl. ¶ 50.

46. DRL does not crystallize omeprazole magnesium by the addition of water. 2nd Brittain Decl. ¶ 50.

47. DRL's process, which relies on evaporating the organic solvent to obtain the omeprazole magnesium, is similar to Example 6 of the prior art '974 patent. 2nd Brittain Decl. ¶ 51.

48. Like Example 6 of the '974 patent, DRL's process relies on the evaporation of the organic solvent -- not the addition of water -- to obtain omeprazole magnesium. 2nd Brittain Decl. ¶ 51.

49. Even though it is possible that the methanol used at the beginning of the DRL process may contain trace amounts of water, DRL does not employ the subsequent step of adding an additional solvent (i.e., water) to precipitate omeprazole magnesium from solution in crystalline form. 2nd Brittain Decl. ¶¶ 51.

50. DRL's process does not include the equivalent of using a different solvent, i.e., water, to recover crystalline magnesium omeprazole salt from an aqueous alcohol solution. 2nd Brittain Decl. ¶¶ 51.

51. The manufacture, importation into the United States, sale, offer for sale and use of the omeprazole magnesium capsules which are the subject of DRL's abbreviated new drug application No. 78-878 do not infringe claims 11 and 20 of the '424 patent, either literally or under the doctrine of equivalents. *See* preceding ¶¶ 42-50.

AstraZeneca Cannot Show That DRL Manufactures Its ANDA Product In The Absence Of Organic Solvents

52. In the 10/7/96 Amendment and Response in the prosecution of the application for the '960 patent, the applicants argued that compared to the prior art their "novel water-based

process" was "environmentally friendly through the absence of organic solvents. . . ." Exhibit 5, p. 8.

53. In claim 10 of the '960 patent the subcoating layer in step (b) is applied in the absence of organic solvents. Exhibit 5, p. 8; 2nd Brittain Decl. ¶ 26.

54. The subcoating solution used in applying the subcoating layer of DRL's ANDA product is a solvent-based system that uses two organic solvents. 2nd Brittain Decl. ¶ 42.

55. DRL's solvent-based process for applying its subcoating layer is not the equivalent of a process that is conducted in the absence of organic solvents. 2nd Brittain Decl. ¶ 53.

56. The manufacture, importation into the United States, sale, offer for sale and use of the omeprazole magnesium capsules which are the subject of DRL's abbreviated new drug application No. 78-878 do not infringe claim 10 of the '960 patent, either literally or under the doctrine of equivalents. *See* preceding ¶¶ 52-55.

IV. DRL Should Be Granted Summary Judgment Of Noninfringement

57. Each dependent claim of the '424 patent depends from at least one of claims 1, 11 and 20 of the '424 patent. Exhibit 2.

58. The manufacture, importation into the United States, sale, offer for sale and use of the omeprazole magnesium capsules which are the subject of DRL's abbreviated new drug application No. 78-878 do not infringe any claim of United States Patent 5,900,424, either literally or under the doctrine of equivalents. *See* preceding, ¶¶ 41, 51 and 57.

59. Each dependent claim of the '960 patent depends from at least one of claims 1, 10 and 22 of the '960 patent. Exhibit 3.

60. The manufacture, importation into the United States, sale, offer for sale and use of the omeprazole magnesium capsules which are the subject of DRL's abbreviated new drug application No. 78-878 do not infringe any claim of United States Patent 5,690,960, either literally or under the doctrine of equivalents. *See* preceding ¶¶ 41, 56 and 59.

Dated: July 9, 2008

Respectfully submitted,

s/ Louis H. Weinstein
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CERTIFICATE OF SERVICE

I certify that on this 9th day of July, 2008, I caused a true and correct copy of DRL DEFENDANTS' STATEMENT PURSUANT TO LOCAL CIVIL RULE 56.1 IN SUPPORT OF DRL'S MOTION FOR SUMMARY JUDGMENT to be served upon counsel for AstraZeneca in the following manner:

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